IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LOUISIANA WHOLESALE DRUG COMPANY, INC. on behalf of itself and all others similarly situated, Plaintiff, v. MERCK & CO., INC., CANCER RESEARCH TECHNOLOGY LIMITED, and SANOFI-AVENTIS, Defendants.	Civil Action No. JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, Louisiana Wholesale Drug Company, Inc. ("Plaintiff" or "LWD") on behalf of itself and all others similarly situated, for its Class Action Complaint ("Complaint") against defendants Merck & Co. Inc., Cancer Research Technology Limited, and Sanofi-Aventis, (collectively "Defendants"), allege as follows based on: (a) personal knowledge; (b) the investigation of its counsel, including review of various pleadings, court orders and the ruling in the patent infringement litigation in this district, discussed herein; and (c) information and belief:

I. NATURE OF THE ACTION

1. This civil antitrust action seeks treble damages for a class of Direct Purchasers who purchased Temodar®, a brain cancer drug, directly from Defendant Merck & Co. Inc. at supracompetitive and monopolistic prices as a result of Defendants' violation of antitrust law.

Temodar® is claimed by U.S. Patent 5,260,291 (the '291 patent), which covers temozolomide, the active ingredient in Temodar®. Defendants engaged in a comprehensive anticompetitive scheme to delay the issuance date (and thereby extend the expiration date) of the '291 patent to unlawfully maintain and/or expand a monopoly in the temozolomide market. Defendants' conduct included: (i) artificially delaying the prosecution of the '291 patent by at least nine years through a series of strategic manipulations of the patent application process to extend improperly the time during which Defendants' could charge (or otherwise benefit from) supracompetitive prices for products claimed by the patent; (ii) deliberately shirking their duty of candor to the PTO to the extent it was inconsistent with their scheme; (iii) improperly listing the '291 patent in the FDA's Orange Book despite knowledge that the '291 patent was unenforceable as a result of prosecution laches; and (iv) knowingly filing sham patent litigation against a generic competitor, Barr Laboratories, Inc. ("Barr"), which has now been acquired by Teva, in order to invoke the 30-month stay of the FDA's approval of Barr/Teva's generic product.

2. Defendants' scheme was grounded in their desire to coordinate several benefits by improperly manipulating the patent statute and regulations, the Hatch-Waxman statute and regulations, and the court system. First, Defendants sought the contradictory, mutually exclusive benefits of: (1) of an early filing date for purposes of overcoming invalidity challenges to the '291 patent and (2) a late patent issuance through unreasonable and inexcusable delays that would best align the '291 patent term with the commercialization of temozolomide. Defendants understood that whether a patent's claims are invalidated by other publicly available "prior art" will turn on the effective filing date for the patent at issue. Accordingly, Defendants filed their patent application in 1982, shortly after the "invention" was conceived, to ensure that their patent

would not be invalidated or prevented by any subsequent disclosures. At the same time, Defendants also understood the benefit of delayed patent issuance because (under the law as it existed at that time) a patent's term commences on the date of patent issuance regardless of whether or not the patent holder can start to commercially exploit the patent. Thus, Defendants understood that: (a) it was possible that some, if not all, of the patent monopoly might expire before the Defendants could gain any value from it; and (b) to optimize the commercial value of the '291 patent Defendants needed to time its issuance to coincide with their ability to financially exploit the patent by commercially developing product(s) claimed by the patent. Recognizing in 1982 that commercialization of any products covered by the potential patent was far off, Defendants engaged in a variety of improper tactics at the United States Patent and Trademark Office ("PTO") designed to extend the prosecution and delay the issuance of the '291 patent.

3. Defendants accordingly sought to abuse the patent application process by seeking to simultaneously gain the benefit of an early patent application (which would give them priority over any subsequent inventor who might seek to develop and/or market a product within the broad scope of the '291 patent claims and also avoid the risk that subsequent public disclosures could render the invention unpatentable), while at the same time strategically delaying the patent's issuance so that the patent's monopoly term would cover a much more commercially lucrative period.

4. The United States District Court for the District of Delaware has already decided, following a full trial, that Defendants' conduct before the PTO constituted prosecution laches rendering the '291 patent unenforceable, that the reasons given for the delay were "not objectively reasonable," and that the delay "cannot be explained by reference to legitimate

considerations and /or expectations." *Cancer Research Tech. v. Barr Labs., Inc.*, 2010 U.S. Dist. LEXIS 6222 (D. Del. Jan. 26, 2010).

5. Defendants' attempt to strategically extend the period of time during which they could exercise their monopoly power by charging supra-competitive prices for Temodar® is also in violation of federal antitrust law. It is well established law that a patentee cannot delay the issuance of a patent for the purpose of maximizing its commercial value (*e.g.* extending the period of time for which the patent holder can charge monopolistic prices) and thereby deprive the public of the free use of the patent which the law intended. *Woodbridge v. United States*, 263 U.S. 50 (1923).

6. Defendants also committed other acts which exploited and extended the initial improper conduct before the PTO, including improperly listing the '291 patent in the Food and Drug Administration ("FDA") Orange Book and filing an objectively baseless and improper patent infringement suit to delay the FDA approval of a competing, generic version of Temodar. As alleged more fully below, because Defendants' delay in prosecuting the '291 patent was objectively unreasonable (rendering the patent unenforceable), the patent should not have been listed in the Orange Book. Absent listing of the '291 patent in the Orange Book, a generic manufacturer would not have been required to submit a Paragraph IV certification, Defendants could not have filed an infringement action under section 271(e)(2)(A) of the Patent Act because there would have been no cognizable act of infringement, and the FDA would have been required to act on an ANDA application seeking to market generic Temodar® within 180 days of submission. Further, Defendants' filing and prosecution of infringement litigation against generic manufacturer Barr/Teva relating to the '291 patent, which triggered an automatic 30-

month stay on FDA approval of Barr/Teva's generic product constituted sham litigation within the meaning of *Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1983) because the patent was clearly unenforceable. Additionally, even if a reasonable litigant could have concluded (contrary to the District Court's finding) that the '291 patent was enforceable for some limited period of time notwithstanding the Defendants' strategic delay in prosecuting the patent, any objective litigant would still recognize that: (a) the patent delays were unreasonable, illegitimate, improper and in bad faith; (b) the patent's 2014 expiration date was artificially extended by the improper conduct before the PTO; and (c) the lawsuit against Barr/Teva were extensions of the prior PTO misconduct by attempting to enforce a patent beyond its legitimate expiration date. In so doing, the Defendants used the lawsuit to exercise the improperly expanded monopoly power to charge supra-competitive prices which stemmed from the earlier misconduct. *DiscoVision Associates v. Disc Mfg., Inc.,* 1997 WL 309499 (D.Del. Apr. 3, 1997) (Robinson) (If a patent holder "seeks to expand the monopoly granted by the patent laws by misuse, agreement, or accumulation" he may incur antitrust liability) (citing *Westinghouse Electric Corp.,* 648 F.2d at 647).

7. As a result of the anticompetitive conduct alleged herein, Defendants unlawfully: (1) maintained and/or artificially expanded their monopoly power in the market for temozolomide (Temodar® and generic versions of Temodar®) in the United States; (2) fixed, raised, maintained, and/or stabilized the price of temozolomide at supra-competitive levels; and (3) overcharged Plaintiff and other direct purchasers of Temodar® by depriving them of the benefits of competition from cheaper generic versions of Temodar®.

II. JURISDICTION AND VENUE

8. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages and the costs of suit and reasonable attorneys' fees, for the injuries sustained by LWD and members of the Class of direct purchasers of Temodar® from Defendants (defined below) resulting from violations by the Defendants, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

9. Defendants transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

10. Plaintiff LWD is a corporation organized under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. LWD purchased Temodar® capsules directly from Defendant Schering/Merck during the Class Period as defined below and was injured by the illegal conduct described herein.

11. Defendant Merck and Co., Inc. ("Merck"), is a company incorporated under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889-0100. Merck develops, manufacturers, and markets pharmaceuticals and related products in the United States. On or about March 9, 2009, Merck acquired Schering Corporation ("Schering") which is the exclusive licensee of the '291 patent. References to Schering herein include Merck.

12. Defendant Cancer Research Technology Limited ("CRT") is a limited liability company organized and existing under the laws of the United Kingdom, having its principal place of business at Sardinia House, Sardinia Street, London, WC2A 3NL, England. Upon information and belief, CRT was formerly known as Cancer Research Campaign Technology Limited ("CRCT"). In October 2002, Cancer Research Campaign Technology Limited underwent a name change to Cancer Research Technology Limited.

13. Defendant Sanofi-Aventis is a corporate entity located at 174, avenue de France, 75635 Paris, France. Upon information and belief, May & Baker ("M&B") assigned the '291 patent to CRT. M&B was acquired by Sanofi-Aventis in connection with a 2004 merger. References to M&B herein include Sanofi-Aventis.

IV. CLASS ACTION ALLEGATIONS

14. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities in the United States who purchased Temodar® in any form directly from the Defendants at any time during the period from March 5, 2006, through the date on which the anti-competitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries or affiliates, and all federal governmental entities.

15. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in the hundreds. Further, the Class is readily identifiable from information and records in the possession of Defendants.

16. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for temozolomide and were deprived of the benefits of competition from cheaper generic versions of Temodar® as a result of Defendants' wrongful conduct.

17. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

18. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

19. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

20. Questions of law and fact common to the Class include:

a. whether Defendants unlawfully maintained monopoly power by delaying generic entry;

b. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

c. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

d. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

e. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

21. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

22. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved

23. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

24. In 1984, Congress amended the Federal Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

25. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

26. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand-name drug.

27. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand-name drug for up to 30 months if the brand-name manufacturer sues a generic manufacturer that files an ANDA application. As discussed below, this statutorily created opportunity to bring a lawsuit *before* the generic drug is approved by the FDA benefits a brand-name manufacturer because otherwise it could not sue for patent infringement until the generic manufacturer's product had been approved by the FDA and was actually sold on the market. Moreover, the 30-month stay on FDA approval that is automatically invoked once a Hatch-Waxman lawsuit is filed further benefits the brand-name manufacturer because it is not

required to meet the rigorous standards for a preliminary injunction to keep the generic product off the market.

28. When the FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book," any patents which the NDA holder contends both (1) claims the drug or the approved use of the drug and (2) could reasonably be asserted if an unlicensed person engaged in the manufacture, use or sale of the drug 21 U.S.C. §355(j)(7)(A)(iii); 21 U.S.C. §355(b)(1). In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand-name manufacturer, but trusts that the manufacturer will be truthful.

29. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand-name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

30. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

31. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand-name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval of the ANDA until the earlier of either: (a) 30 months; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand-name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand-name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

B. Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions

32. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand-name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand-name product unless the doctor has indicated that the prescription for the brand-name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generic accelerates. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong interest to use the tactics alleged above to delay the introduction of generic competition into the market.

C. Defendants Strategically Delayed the Issuance of the '291 Patent To Their Own Commercial Advantage[1]

33. The '291 patent, entitled "Tetrazine Derivatives," contains 33 claims: 26 to tetrazine derivatives (claims 1-26); one to a pharmaceutical composition (claim 27); and six directed to methods of use relating to specific cancers (claims 28-33).

34. The '291 patent specification purports to provide "new therapeutically useful compounds possessing antineoplastic and immunomodulatory activity." ('291 patent, Abstract) The specification proceeds to identify thirteen "[i]mportant individual compounds of general formula I," labeled as compounds A through M. *(Id.,* col. 4, l. 59 - col. 5, l. 16). According to the patent, [c]ompounds A and D, and especially C, are of **particular importance**." *(Id.,* col. 5, ll.17-18) (emphasis added) Compound A is temozolomide (the active ingredient in Temodar®); compound C is mitozolomide (the first compound tested by the applicants in animals and humans); and compound D is a mitozolomide-related compound. Each compound is individually claimed.

35. The '291 patent names five purported inventors: Edward Lunt ("Lunt"), Malcolm F. G. Stevens ("Stevens"), Robert Stone ("Stone"), Kenneth R. H. Wooldridge ("Wooldridge"), and Edward S. Newlands ("Newlands"). Stevens and Stone are medicinal chemists who developed tetrazine derivatives beginning in 1980 pursuant to a collaborative agreement between Aston University ("Aston") in England and May & Baker ("M&B"), a U.K.-based pharmaceutical company. Stevens was a professor of experimental cancer chemotherapy at Aston University; Stone was an Aston University Ph.D. candidate. Lunt and Wooldridge were

[1] Paragraphs 33 through 60 of this Complaint are drawn directly from the District Court's findings of fact. *Cancer Research Tech. v. Barr Labs., Inc.*, 2010 U.S. Dist. LEXIS 6222 (D. Del. Jan. 26, 2010). ¶¶ 3-4, 7-34.

employees of M&B who were involved in the preclinical testing of a number of the tetrazine derivatives. Newlands was added to the application in 1993 based on his work on the clinical testing of temozolomide in glioma. In connection with the patent application, each inventor signed a Declaration acknowledging his duty to disclose material information to the PTO.

1. Prosecutorial timeline and relevant events

36. The first application in the series leading to the '291 patent, U.S. Patent Application No. 06/410,656 ("the '656 application"), was filed August 23, 1982 - one year after the filing of British Patent Application No. 8125791 on August 24, 1981. M&B's British patent counsel was Stephen Bentham ("Bentham") of the firm J.A. Kemp & Co.

37. The '291 patent, which issued November 9, 1993, claims priority to the filing of the '656 application through a chain of continuing applications as described below.[2] The '291 patent expires in February 2014, almost thirty-two years after the first application in this chain was filed. All together, the prosecution of the '291 patent involved eleven patent applications, ten of which were abandoned.

38. Terry Miller ("Miller"), a patent manager at M&B, was responsible for the prosecution of the '656 application and subsequent applications from August 1982 until approximately March 1991. The '656 application was filed August 23, 1982 by U.S. patent attorney Ellsworth Mosher ("Mosher"). Examiner John M. Ford was assigned the '656 application.

[2] The 29 as-filed claims of the '656 application mirror the issued claims 1-29 of the '291 patent.

39. An office action was mailed in the '656 application on November 18, 1983.[3] Examiner Ford issued a utility rejection based on the "Medical Use" provision formerly found at MPEP 608.01 (p). The MPEP stated as follows:

> Proof of utility under this section [608.01 (p)] may be established by clinical or in vivo or in vitro data, or combinations of these, which would be convincing to those skilled in the art .... More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, (Ex parte Timmis, 123 U.S.P.Q. 581) although animal tests may be adequate where the art would accept these as appropriately correlated with human utility .... or where animal tests are coupled with other evidence, including clinical evidence and a structural similarity to compounds marketed commercially for the same indicated uses[.]

Examiner Ford explained the rejection as follows.

> Statements of utility which relate to or simply imply the treatment of a disease are subject to closer scrutiny ... Thus, when the disclosed utility is the production of a physiological response, e.g., antidepressant effect, the dosage effective to achieve this response, whether human or animal, must be disclosed ....
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> The District Court for the District of Columbia held the patent office should be careful and perhaps even reluctant to grant a patent on a medicinal composition until it has been thoroughly tested and tried by several physicians, on the theory that some members of the public would rely on the "official imprimatur" given to the medicin[e] by the granting of a patent thereon. *Issenstead v. Watson,* (DCDC 1957) F. Supp. 7, 115 U.S.P.Q. 408[.]
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> The treatment of leukemia is not a believable utility on its face .... The [B]oard of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof, when such use is of a medical nature [] for the treatment of serious disease, such as cancer. *Ex parte Moore et al.,* (POBA 1960) 128 U.S. P.Q. 8; *In re Citron,* (CCPA 1964) 325 F.2d 248, 139 U.S.P.Q. 516; *In re Hartop et al.,* (CCPA 1962) 311 F.2d 249,135 U.S. P.Q. 419.

[3] During the trial Barr highlighted this action as exemplary of all the remaining office actions in the case.

> Remission of a specific leukemia could be establish[ed], but has not been so accomplished here or so claimed.

40. No response was filed to the November 18, 1983 office action in the '656 application. U.S. Patent Application No. 06/586,635 ("the '635 application"), a continuation of the '656 application, was then filed by the applicants on March 6, 1984; the '656 application was subsequently abandoned.

41. An office action was issued in the '635 application in October 1984.[4] Examiner Ford was assigned the '635 application, and repeated his arguments made in rejection of the claims in the '656 application.

42. No response was filed. U.S. Patent Application No. 06/712,462 ("the '462 application"), a continuation of the '635 application, was filed by the applicants on March 15, 1985; the '635 application was subsequently abandoned.

43. Examiner Ford was assigned the '462 application and, on June 17, 1985, he issued an office action in the '462 application mirroring that filed in the '656 application. No response was filed. U.S. Patent Application No. 06/798,365 ("the '365 application"), a continuation of the '462 application, was filed by the applicants on November 18, 1985; the '462 application was subsequently abandoned.

44. An office action rejecting the '365 application was issued by Examiner Ford on January 24, 1986. No response was filed. Rather, the applicants filed a continuation application, U.S. Patent Application No. 06/885,397 ("the '397 application") on July 18, 1986, and

[4] The '635 application contained 31 claims. The Examiner noted that restriction was required in the '656 application to one utility to be examined with the compound claims. The applicants elected the method use with respect to the treatment of leukemia. That election carried into the '635 application and, as part of his first office action, the examiner required the applicants to cancel or amend claims 27-30 to read solely on the elected use.

abandoned the '365 application. Examiner Ford was assigned the '397 application and issued a rejection on October 21, 1986.

45. In lieu of a response, applicants filed U.S. Patent Application No. 07/040,716 ("the '716 application"), another continuation application, on April 20, 1987. Examiner Ford issued a rejection on August 19, 1987.

46. U.S. Patent Application No. 07/135,473 ("the '473 application"), a continuation application, was filed on December 21, 1987. The '716 application was subsequently abandoned. Examiner Ford was assigned the '473 application and issued a rejection on October 4, 1988, reiterating that "[t]he treatment of leukemia is not a believable utility on its face," and issuing a best mode rejection stating the following:

> Claim 1 is rejected under 35 U.S.C. [§]112. In the definition of R1, note "optionally substituted phenyl." What is the phenyl "optionally substituted" with? No actual best mode of using the compounds is seen in pages 29-31 of the specification. **There is still a best mode requirement....No in vivo or in vitro tests are noted. No tests in laboratory animals are noted.**
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> *Brenner v. Manson,* 148 U.S.P.Q. 689, requires more than a laboratory curiosity. The compounds need to be related to the practical world of commerce. Repeated disclosure of how to make a solution for parenteral administration or a capsule does not disclose the best mode intended for how to **use** the instant compounds for a specific purpose, among the many alleged.

(first emphasis added). Applicants did not respond. U.S. Patent Application No. 07/338,515 ("the '515 application") was filed on March 3, 1989 as a continuation application, and the '473 application was abandoned.

47. The '515 application was examined by Examiner Johann Richter, a supervisory patent examiner in Examiner Ford's art unit. On June 30, 1989, Examiner Richter issued an office action rejecting the claims on utility, enablement, and best mode grounds; the action was

made final. With respect to utility, Examiner Richter repeated Examiner Ford's reasoning that the treatment of leukemia or cancer is not believable on its face. Examiner Richter also reiterated that the Board has held that "even though the specification does not mention human use specifically, the [PTO] is not precluded from finding an inference of human use and require proof thereof, when such use is of a medical nature for the treatment of a serious disease, such as cancer."

48. Again, applicants filed a continuation application in lieu of a response. U.S. Patent Application No. 07/456,614 ("the '614 application") was filed December 29, 1989, and the '515 application was abandoned.

49. Examiner Richter issued a rejection in the '614 application on May 1, 1990, wherein he repeated his utility and 35 U.S.C. § 112 rejections.[5] No response was filed. On November 1, 1990, Mr. Calavetti of Morgan & Finnegan filed on behalf of the applicants a continuation application, U.S. Patent Application No. 07/607,221 ("the '221 application"). The '614 application was abandoned.

50. U.S. Patent Application No. 07/781,020 ("the '020 application") was filed as a continuation-in-part from the '221 application on October 18, 1991. The '020 application ultimately matured into the '291 patent.

51. On October 18, 1991, Attorney Rzucidlo of Morgan & Finnegan filed a Preliminary Amendment and Remarks with the '020 application addressing the utility rejection, stating:

[5] Although the preceding office action was a final rejection, neither this action nor subsequent office actions were made final.

> It is believed that this rejection should be reconsidered in view of the disclosure of other utilities for the present compounds as well as the disclosure at page 8 and 9, connecting paragraph **wherein the effectiveness of the present compounds is demonstrated**. (emphasis added)

2. Licensing activities and the '020 application

52. Prior to 1991, M&B had decided that mitozolomide [compound C] was not a favorable candidate. M&B decided not to pursue studies with mitozolomide due to the toxic side effects seen in the phase I trials.

53. By this time, Stevens, Newlands, and other colleagues in this field had obtained positive results with temozolomide. In March 1989, the "Sixth NCI-EORTC symposium on new drugs and cancer therapy" was held in Amsterdam. An abstract from that conference, entitled "Phase I trial of temozolomide,"[6] is informative on the state of the art at that time.

> A number of 3-alkyl analogs of the experimental antitumour drug mitozolomide have been screened against murine tumors in vivo. Only the compounds with a 3-methyl- or 3-bromoethyl group possessed significant antitumor [effects] against the TLXS lymphoma. The 3-methyl analogue, 8-carbamoyl-3-methylimidazo[S,1-d]-1 ,2, 3,S-tetrazin-4(3H)-one (temozolomide) was investigated further and found to possess good activity when administered i.p. against the L1210 and P388 leukemias, the MS076 reticulum cell sarcoma, B126 melanoma and ADJ/PC6A lasmacytoma. The drug was also active when administered p.o. to mice bearing the L1210 leukemia ... Mitozolomide underwent phase II testing in Europe but its development has been stopped owing to unpredictable and prolonged thrombocytopaenia. Temozolomide was chosen for development since it is thought to spontaneously activate to MTIC which is a potent alkylating agent[.]
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> Two clinical improvements were observed [with temozolomide]: one in a patient with malignant melanoma and the other had squamous cell carcinoma of the head and neck but neither was a partial response.

[6] By Newlands and R. Hoffman of Charing Cross Hospital in London, U.K., J. Slack, C. Quartermain and Stevens of Aston University, and Blackledge and N. Stuart of Queen Elizabeth Hospital in Birmingham, U.K.

("temozolomide showed broad spectrum activity" and "increased therapeutic activity against both P388 and L1210 leukemias") (1990); (Phase I testing of temozolomide revealed "clinical activity ... in two patients with melanoma (1 CR at 10+ months and 1 PR at 7+ months) and a complete response in mycosis fungoides lasting 3+ months") (1990)).

54. Despite M&B's decision not to pursue mitozolomide the work on tetrazine derivatives continued. Stevens spoke with Dr. Sue Foden ("Foden") of CRT, which had sponsored the phase I trial of temozolomide, about CRT's securing ownership of the rights to tetrazine derivatives. M&B and Cancer Research Campaign Technology ("CRCT"), a small subsidiary of CRT, executed a licensing agreement on March 26, 1991.

55. CRCT could not commercialize temozolomide itself. After securing the patent rights, CRCT embarked on a "road show," a series of visits to pharmaceutical companies in the United States (including Schering), in an attempt to find a pharmaceutical partner to develop temozolomide.

56. Schering decided to pursue temozolomide. CRCT and Schering first entered into a "shutout agreement" to allow them to further negotiate the licensing of temozolomide. Ultimately, the negotiations resulted in a June 1992 exclusive licensing agreement between the parties. Under that agreement, Schering/Merck pays CRCT a royalty percentage of net sales of temozolomide, and CRCT pays portions of that royalty to M&B, Aston University, and Charing Cross Hospital; the remainder is used to fund further cancer research.

57. After Schering and CRCT formalized their license agreement, responsibility for the '020 patent application was transferred to the law firm of Klauber & Jackson, which handled other oncology applications for Schering.

58. On August 6, 1992, Examiner Richter issued an office action in the '020 application. With respect to 35 U.S.C. § 112,¶1, Examiner Richter stated:

> The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof, when such use is of a medical nature [ ] for the treatment of serious disease, such as cancer. *Ex parte Moore et al.,* (POBA 1960) 128 U.S.P.Q. 8; *In re Citron,* (CCPA 1964) 325 F.2d 248, 139 U.S.P.Q. 516; *In re Harlop et al.,* (CCPA 1962) 311 F.2d 249, 135 U.S.P.Q. 541.
>
> Remission of a specific leukemia could be established, but has not been so accomplished or so claimed.

59. On February 5, 1993, Attorney Barbara L. Renda of Klauber & Jackson submitted, together with a request for an extension of time, a substantive response to the pending office action - the first substantive response filed in the entire chain of applications. With respect to the § 112, ¶1 rejection, Attorney Renda cited the relevant language of *Ex parte Krepelka* and asserted that:

> [a] [c]omparison of the facts of *Krepelka* to those of the instant Application would lead to the inescapable conclusion that claims 1-28 are patentable to Applicants **based upon the results of animal testing given at lines 9-26 of page 8 and lines 1-8 at page 9.** (emphasis added).

That is, despite the passage of over a decade, the applicants did not provide additional data in support of patentability; they pointed to animal data in the original specification.

60. On April 16, 1993, a Notice of Allowability was issued by Examiner Bernard Dentz, a Primary Patent Examiner. Examiner Dentz provided the following statement of reasons for allowance: "As evidence to support the utility of the instant compounds the article of Lunt and others from the Journal of Medicinal Chemistry is made of record." This citation was to a 1987 article by inventor Lunt and others, entitled "Antitumor Imidazotetrazines. 14. Synthesis

and Antitumor Activity of 6- and 8-Substituted Imidazo[5,1-d]-1,2,3,5-tetrazinones and 8-Substituted Pyrazolo[5,1-d]-1,2,3,5-tetrazinones" (hereinafter, "the Lunt article"). The Lunt article was not cited by the applicants, but discovered independently by Examiner Dentz. It did not disclose human data, but showed activity of mitozolomide and other related compounds against tumors in mice.

61. Defendants' scheme also involved inequitable conduct before the PTO. Given the representations and history of rejections in the applications leading to the '291 patent, Renda's argument in favor of utility, and the PTO examiner's rationale for allowing the patent to issue, a reasonable examiner would undoubtedly consider highly relevant any evidence undercutting the ability of the claimed compounds to treat cancers of the type addressed in the applications leading to the '291 patent.

62. Such evidence existed and was known to at least Stevens and Stone. For example, they were aware of a handwritten chart comparing the activities of several mitozolomide analogs, dated July 19 1983, indicating that structures corresponding to compounds B, E, F, G, J, and K in the '291 patent were "inactive" against TLX5 tumors.

63. In 1985, Stevens and Stone co-authored an article reflecting their recognition that mitozolomide, temozolomide, and a 3-(2-bromethyl-) derivative had only "marginal" activity against TLX5 lymphoma in mice and that the "other 3-alkyl analogues [tested] are **all inactive** against this tumor on a single dose schedule." The "inactive" compounds included compounds B, E, F, G, J and K in '291 patent.

64. Stevens also authored several publications prior to Renda's argument reflecting the inactivity of claimed compounds in other cancers. For example, in 1986, Stevens and his

colleagues submitted an article to the Cancer Research Journal in which the activity of several experimental compounds on the TLX5 tumor strain in mice was noted. Structures corresponding to claimed compounds B, K, E, F, and G from the applications leading to the '291 patent were reported to have unacceptable levels of activity. Similarly, a 1987 book chapter authored by Stevens included a table specifically listing six of the purportedly "important" mitozolomide analogs of the '291 patent as "inactive." Also, a 1990 book chapter co-authored by Stevens, Newlands and Blackledge describes the phase II studies undertaken with mitozolomide as "negative with no responses being seen" and "no evidence of activity." A 1987 article discussed the treatment of 25 (previously treated) advanced ovarian cancer patients with mitozolomide and reported that two patients died due to toxicity and that no tumor remissions were achieved. The article further concluded that "mitozolomide produces unacceptable haematological toxicity and has no anti-tumor activity in previously treated patients with ovarian cancer." A 1988 article reported phase II results for twenty-two patients with advanced colorectal cancer and fourteen with breast cancer, noting no response, and concluding that "mitozolomide ... does not show activity in human CRC [colorectal cancer] and in pretreated BC [breast cancer]," not precluding a "marginal activity of the drug as a first line therapy in [breast cancer]." Yet another 1988 phase II study of fifteen patients with advanced bladder cancer resulted in no responses and unacceptable myelotoxicity and noted that "[r]esponses to mitozolomide have been seen in lung cancer and melanoma but other tumor types appear to be resistant to the doses that can be reasonably administered." A 1989 phase II study for mitozolomide in treating patients with advanced renal cell carcinoma yielded no complete or partial responses.

65. The foregoing publications, articles and evidence were highly material to the prosecution of the '291 patent because (1) they were inconsistent with both the representations in the applications leading to the '291 patent and the argument made in favor of patentability by Renda; (2) they were inconsistent with the reasons for allowance provided by the Examiner and (3) they would have both reinforced the utility rejection by the PTO and justified an enablement rejection as to at least some of the claims that issued in the '291 patent.

66. As found by the Court, despite the very high materiality of this evidence, neither the applicants nor their attorneys ever disclosed to the PTO any data or publications indicating that the "particular[ly] importan[t]" compound mitozolomide did not treat colorectal and breast carcinoma, bladder cancer, ovarian adenocarcinoma, or renal cell carcinoma covered by claim 28. Likewise, the PTO was also never informed that several of the purportedly "important" mitozolomide analogs, such as compounds B, E, F, G, J, and K were deemed "inactive" by the inventors, at least in TLX5 lymphoma, which again was covered by claim 28. Furthermore, the applicants never disclosed to the PTO that mitozolomide had a demonstrable toxicity in phase II trials. Accordingly, the Court deemed this withheld information "highly material."

67. The failure to disclose this evidence was not an oversight, but rather was the product of an intent to deceive the PTO by at least Stevens, and possibly by others. The Court has already found that Stevens knew of the withheld information and should have appreciated its high level of materiality. The Court has further rejected arguments made by Defendants supporting Stevens' purported good faith in failing to disclose the highly material information to the PTO. Accordingly, the Court found the requisite intent necessary to support a holding of inequitable conduct.

68. The '291 patent issued on November 9, 1993. Schering/Merck filed for a patent term extension based on the time that it took to get FDA approval for temozolomide and was granted an extension of 1006 days (the maximum allowed by law). Schering/Merck was also granted pediatric exclusivity which extends the '291 patent expiration date until February 11, 2014, thirty-two years after the filing of the initial patent application.

D. Merck Obtains FDA Approval To Market Temodar® and Uses the '291 Patent to Delay Barr/Teva's ANDA to market a Generic Version Of Temodar®

69. On December 17, 1993, a little over a month after the '291 patent was issued, Schering/Merck submitted its investigational new drug application for temozolomide to the FDA. NDA #21-209.

70. On August 11, 1999, the FDA granted Schering/Merck approval to market Temodar® (temozolomide capsules) for the treatment of adult patients with refractory anaplastic astrocytoma ("AA").

71. On or about August 12, 1999, Schering/Merck began marketing Temodar®.

72. Prior to marketing Temodar®, Schering/Merck submitted the '291 patent for listing in the Orange Book. In doing so, Schering/Merck represented to the FDA that the '291 patent (1) claims the drug Temodar® or an approved method of use of Temodar® and (2) could reasonably be asserted if an unlicensed person engaged in the manufacture, use or sale of the drug. 21 U.S.C. § 355(b)(1). As a result of the listing of the '291 patent in the Orange Book, any drug manufacturer seeking to submit an ANDA to market a generic version of Temodar® prior to the expiration of the '291 patent was required to submit a Paragraph IV certification that the patent was invalid, unenforceable or not infringed by the generic product. The filing of an

ANDA with a Paragraph IV certification creates a cause of action for infringement if the brand manufacturer initiates a patent infringement action within 45 days of receiving the Paragraph IV certification. Absent an ANDA with a Paragraph IV certification, Schering/Merck would have no basis to bring an infringement action until the alleged infringer actually markets the allegedly infringing product. Additionally, if there is no patent listed in the Orange Book with respect to an approved drug, an ANDA filer is only required to submit a Paragraph I certification and the FDA must act within 180 days, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5).

73. Moreover, if the patent holder does bring an infringement action within 45 days of receiving notice of the generic drug manufacturer's ANDA, the FDA may not grant final approval to the generic product until the earlier of either: (a) 30 months from the date notice of the ANDA is received by the NDA holder; or (b) a decision by a court that the patent is invalid or not infringed by the generic manufacturer's product. 21 U.S.C. § 355(j)(5)(B)(iii). The automatic 30-month stay is the equivalent of a preliminary injunction that the patent holder receives without any required showing that an injunction is appropriate.

74. On March 19, 2007, Barr/Teva filed an ANDA (No. 78-879) and Paragraph IV certification with the FDA seeking approval to engage in the manufacture, use or sale of generic temozolomide capsules.

75. Pursuant to that certification, Barr/Teva sent to Schering/Merck and CRT the statutorily-required notice letter containing a detailed factual and legal statement as to why the '291 patent was invalid, unenforceable and/or not infringed by Barr/Teva's ANDA. Upon information and belief, Barr/Teva's paragraph IV letter advised Schering/Merck and CRT,

among other things, that the '291 patent was unenforceable for prosecution history laches. Moreover, upon information and belief, Merck had already learned about the prosecution history of the '291 patent in 1992 when it acquired an exclusive license for the patent from CRT.

76. On July 20, 2007, Schering/Merck and CRT filed an infringement action in the United States District Court for the District of Delaware alleging that Barr/Teva's ANDA infringed the '291 patent. By doing so, Schering/Merck invoked the 30-month stay on FDA approval of Barr/Teva's product.

77. During the course of the '291 patent litigation, Schering/Merck was made repeatedly aware that Barr/Teva claimed that the '291 patent was unenforceable due to prosecution laches among other reasons. For example, in Barr/Teva's Answer, Affirmative Defenses and Counterclaims to Schering/Merck's complaint (filed on August 13, 2007), Barr/Teva asserted the affirmative defense that "all of the claims of the '291 patent are unenforceable because of prosecution history laches and sought a declaratory judgment on the grounds that the '291 patent was unenforceable because of prosecution laches.

78. A bench trial was held between March 30, 2009 and April 2, 2009 on two unenforceability defense raised by Barr/Teva: prosecution laches and inequitable conduct. These issues were fully briefed post trial and on January 26, 2010 the United States District Court for the District of Delaware found that the '291 patent unenforceable due to prosecution laches and/or inequitable conduct.

79. With respect to the issue of prosecution laches the Court found, among other things, that

> (i) CRT did "nothing" to further the prosecution of [its] application toward the issuance of any claims' for nearly a decade and, instead preserved its rights through a series of continuation and abandonments;
>
> (ii) Taken in the totality, the case involved "eleven patent application, ten abandonments and no substantive prosecution for a decade";
>
> (iii) CRT's primary justification for delay, that neither of [the patent examiners] would have allowed the applications at issue absent human data, is not objectively reasonable in view of the fact that CRT never attempted to traverse the rejections (thereby either validating its position or obtaining allowance of its claims);
>
> (iv) CRT's delay therefore cannot be explained by reference to legitimate consideration and/or expectations;
>
> (v) CRT introduced no contemporaneous evidence substantiating its position or establishing that CRT sought to develop the technology prior to the [Merck] license;
>
> (vi) CRT only engaged the PTO once it had a profit motive to do so; and
>
> (vii) Defendants' conduct was "sufficiently egregious to warrant rendering the '291 unenforceable due to prosecution laches."

80. Accordingly, because there was no objectively reasonable basis to believe that the '291 patent was enforceable as a result of the egregious conduct delaying the prosecution of the patent for over nine years, there was no objectively reasonable or legitimate basis to list the '291 patent in the Orange Book and file and prosecute infringement litigation against Barr/Teva with respect to the '291 patent. Under well-established patent law, "a patent applicant may not delay in prosecuting a patent for the purpose of making the term of the monopoly square with the period when the commercial profit from it would be the highest." *Woodbridge v. United States*, 263 U.S. 50 (1923).

81. Additionally, even if a reasonable litigant could have concluded (contrary to the District Court's finding) that the '291 patent was enforceable for some period of time notwithstanding the Defendants' strategic delay in prosecuting the patent, any objective litigant would have recognized that: (a) the patent delays were unreasonable, illegitimate, improper and in bad faith; (b) the patent's 2014 expiration date was artificially extended by the improper conduct before the PTO; and (c) the lawsuit against Barr/Teva were extensions of the prior PTO misconduct by attempting to enforce a patent beyond its legitimate expiration date. In so doing, the Defendants used the lawsuit to exercise the improperly expanded monopoly power to charge supra-competitive prices which stemmed from the earlier misconduct. *DiscoVision Associates v. Disc Mfg., Inc.,* 1997 WL 309499 (D.Del. Apr. 3, 1997) (Robinson) (If a patent holder "seeks to expand the monopoly granted by the patent laws by misuse, agreement, or accumulation" he may incur antitrust liability) (citing *Westinghouse Electric Corp.,* 648 F.2d at 647).

82. Each of the Defendants is accountable (liable) for the conduct alleged herein since each of the Defendants shared in the unlawful monopoly profits and was aware of its codefendants' conduct in furtherance of the anticompetitive scheme. As the District Court determined, under the patent licensing agreement between CRT and Schering/Merck, Schering/Merck pays CRT a royalty percentage of the net sales of temozolomide and CRT pays portions of that royalty to M&B. Moreover, upon information and belief, both CRT and Schering/Merck were fully aware of M&B's conduct in strategically delaying the prosecution of the '291 for commercial advantage prior to the listing of the '291 patent in the Orange Book and the filing of the infringement lawsuit against Barr/Teva. Prior to executing the March 26, 1991 licensing agreement with M&B, CRT reviewed the patent rights and patent applications that it

was licensing. In that process, CRT reviewed the patent prosecution history regarding what ultimately became the '291 patent. Similarly, Schering/Merck, prior to entering into the "shutout" and patent licensing agreements with CRT in 1992, reviewed all patents and patent applications regarding temozolomide including the full patent prosecution history for the applications that became the '291 patent. Moreover, upon information and belief both CRT and Schering/Merck reviewed Barr/Teva's Paragraph IV certification notice that asserted that the '291 patent was unenforceable because of prosecution laches prior to filing the infringement action and both were aware that Barr/Teva has asserted prosecution history laches as an affirmative defense and counterclaim to the action yet they both filed, prosecuted, and still continue, to prosecute the lawsuit.

E. Defendants' Conduct Is Not Immune Under the *Noerr-Pennington* Doctrine

83. Patent holders can violate antitrust laws if they seek to expand the limited monopoly granted by their patents. *See, e.g. DiscoVision Association v. Disc Mfg., Inc.*, Nos. 95-21 & 95-345, 1997 WL 309499, at (D.Del. Apr. 3, 1997). Courts have held that abuse of the patent prosecution process and inequitable conduct before the Patent Office similar to what is alleged here may form the basis for a viable antitrust claim. *See In re Neurontin Antitrust Litig.*, 2009 U.S. Dist. LEXIS 77475 (D.N.J. Aug. 27, 2009); and *DiscoVision Association,* 1997 WL 309499. In such a situation, anticompetitive injury emanates; and *DiscoVision Association,* 1997 WL 309499.

84. Furthermore, the patent prosecution delays were the result of a series of patent applications and abandonments that were solely within Defendants' control. The PTO's

acceptance of Defendants' patent applications were merely a "ministerial" action which did not involve any substantive review or approval.

85. Similarly, the Noerr-Pennington doctrine does not immunize Defendants' illegal conduct from antitrust liability, because the patent litigation action brought by Defendants against Barr/Teva was an objectively baseless "sham," which no litigant could reasonably have expected to win, and was prosecuted solely for the purpose of delaying entry of generic competition into the market for temozolomide.

F. Effect on Interstate Commerce

86. At all material times, Temodar®, manufactured and sold by Defendant Schering/Merck, was shipped across state lines and sold to customers located outside its state of manufacture.

87. During the relevant time period, in connection with the purchase and sale of Temodar®, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

88. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

G. Monopoly Power

89. Through the anticompetitive conduct alleged herein, Defendants were able to charge supracompetitive prices for temozolomide, and thus, by definition, maintained monopoly power with respect to temozolomide sold in the United States. To the extent that Plaintiffs are

legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is all temozolomide products – i.e., Temodar® (in all its dosage strengths), and bioequivalent temozolomide products. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which temozolomide is prescribed. For the entire period relevant to this case, Defendants have been able to profitably maintain the price of their branded temozolomide products well above competitive levels.

90. The relevant geographic market is the United States and its territories.

91. Defendants' market share in the relevant market is and was 100% at all times prior to the sale of Barr/Teva's branded temozolomide capsules in the United States.

92. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

93. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Temodar® resulted in Plaintiffs and the Class paying more than they would have paid for temozolomide, absent Defendants' illegal conduct.

H. Effects on Competition and Damages to Plaintiffs and Class

94. Defendants' exclusionary conduct has delayed or prevented the sale of generic temozolomide in the United States, and unlawfully enabled Defendants to sell Temodar® at artificially inflated prices.

95. As the United States District Court for the District of Delaware has already determined, Defendants' conduct in delaying the prosecution of the '291 patent and procuring it through inequitable conduct rendered the patent unenforceable.

96. Since Defendants' conduct prior to the '291 patent's issuance rendered the patent unenforceable, there was no basis for listing the patent in the FDA's Orange Book because the patent could not reasonably be asserted against a manufacturer seeking to market a generic version of Temodar®.

97. Because there was no basis to list the '291 patent in the Orange Book, generic manufacturers should not have been required to file Paragraph IV certifications with their ANDAs seeking to market a generic version of Temodar®. Additionally, absent a Paragraph IV certification, a generic manufacturer's filing of an ANDA would not have given Defendants a cause of action to bring an infringement action. Further, absent a Paragraph IV filing, a generic manufacturer would only have been required to file a Paragraph I certification (no patent for the brand name drug) and the FDA would have been required to act on the application within 180 days of receipt, unless both the FDA and applicant agree to extend the deadline. 21 USC 355(j)(5)(A).

98. Moreover, but for the improper filing of the '291 patent in the Orange Book that permitted Defendants to bring an infringement action, *the 30-month stay on FDA final approval of the generic product would not have been applicable.*

99. Additionally, even if it was not improper to list the '291 patent in the Orange Book, the filing and prosecution of the '291 lawsuit – which triggered the 30-month stay – was still objectively unreasonable because Defendants knew of the delay in prosecuting the '291

patent and that a patentee may not deliberately delay the issuance of a patent so that its term and monopoly would reach forward and cover a much more commercially lucrative period than it the patentee had obtained the patent when it might and should have requested it. *See Woodbridge v. United States,* 263 U.S. 50 (1923).

100. Barr/Teva filed its ANDA in March, 2007. It received tentative approval from the FDA in September 2009. But for the 30-month stay that was invoked as a result of the lawsuit, the FDA's grant of tentative approval would have constituted final approval permitting Barr/Teva to immediately market its generic Temodar® product.

101. Accordingly, but for the Defendants' anticompetitive conduct a generic version of Temodar® capsules could have been on the market at least as early as September 2009 (if not earlier), and additional generic competitors would have entered the market thereafter.

102. If manufacturers of generic temozolomide had been able to enter the marketplace and effectively compete with Defendants earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic temozolomide for the higher-priced brand-name Temodar® for some or all of their temozolomide product needs, and/or would have received discounts on some or all of their remaining brand-name Temodar® purchases.

103. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Temodar® directly from Defendant Schering/Merck. As a result of Defendants' illegal conduct alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their temozolomide requirements. Plaintiff and all of the other class members paid prices for temozolomide that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein,

because: (1) class members were deprived of the opportunity to purchase lower-priced generic temozolomide instead of expensive brand-name Temodar®; (2) Class members paid artificially inflated prices for generic temozolomide and/or (3) the price of branded Temodar® was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act:

104. Plaintiff refers to and incorporates herein, the allegations in ¶¶ 1-103 above.

105. Defendants used various willful and exclusionary means as part of an overall scheme described herein to improperly maintain and extend their monopoly power in the temozolomide market, as detailed above.

106. The goal, purpose and/or effect of Defendants' anticompetitive scheme was to strategically delay the issuance of the '291 patent to their own commercial advantage and improperly manipulate the Hatch-Waxman Act to delay the entry of generic temozolomide competitors which would have sold generic temozolomide in the United States at prices significantly below Defendants' prices for Temodar®, and which would have effectively caused the average market price of temozolomide to decline dramatically.

107. Defendants' anticompetitive conduct included the following, each of which separately and in combination constituted violations of Section 2 of the Sherman Act:

(i) strategically delaying the prosecution of the '291 patent so that the term of the patent would cover a much more commercially lucrative period than if the patent had issued earlier;

(ii) failing to comply with the duty of candor owed to the PTO and intentionally deceiving the PTO into issuing the patent by knowingly failing to disclose highly material information to the PTO;

(iii) improperly listing the '291 patent in the Orange Book , when because of the egregious delay in prosecuting the patent and the consequences thereof, a claim of infringement could not reasonably be asserted against a drug manufacturer seeking to market a generic version of Temodar®; and

(iv) filing an objectively baseless and/or otherwise improper lawsuit against a Barr to invoke the 30-month stay on final FDA approval of the generic manufacturer's product.

108. As a result of Defendants' illegal scheme, Plaintiff and the Class paid more than they would have paid for temozolomide, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic versions of Temodar® no later than September 2009.

109. If manufacturers of generic temozolomide had been able to enter the market and compete with Defendants in a full and timely fashion, Plaintiff and other Class members would have substituted lower-priced generic temozolomide for the higher-priced brand-name Temodar® for some or all of their temozolomide requirements, and/or would have received lower prices on some or all of their remaining Temodar® purchases.

110. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Temodar® directly from Schering/Merck. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their temozolomide product purchases. Plaintiff and all of the other class members paid prices for temozolomide products that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1)

class members were deprived of the opportunity to purchase lower-priced generic temozolomide instead of expensive brand-name Temodar®; (2) class members were forced to pay artificially inflated prices for generic temozolomide and/or (3) the price of branded Temodar® was artificially inflated by Defendants' illegal conduct.

111. Defendants' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for temozolomide in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT II

Conspiracy to Monopolize in Violation of Section 2 of the Sherman Act:

112. Plaintiff refers to and incorporates herein, the allegations in ¶¶ 1-111 above.

113. As set forth above, the Defendants conspired with each other and with the specific intent to unlawfully maintain their monopoly power in the temozolomide market by strategically delaying the prosecution of the '291 patent to their own commercial advantage, improperly listing the '291 patent in the Orange Book and filing sham litigation against Barr/Teva to delay and exclude competition. All Defendants committed at least one overt act in furtherance of the conspiracy, which affected interstate commerce.

114. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Temodar® directly from Schering/Merck. As a result of Defendants' illegal conduct alleged herein, Plaintiff and the other Class members paid artificially inflated prices for the drug. Plaintiff and all of the other Class members paid prices for Temodar® that were substantially higher than the prices that they would have paid absent the illegal conduct alleged herein.

COUNT III

Conspiracy in Restraint of Trade in Violation of Section 1 of the Sherman Act:

115. Plaintiff refers to, and incorporates herein, the allegations in ¶¶ 1-114 above.

116. Beginning by or prior to August 1982, Defendants engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to eliminate or delay competition in the temozolomide market enabling Defendants to fix the prices which direct purchasers paid for Temodar®.

117. By their conduct, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

118. Plaintiff and the members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Temodar® directly from Defendants. Plaintiff and the Class members have paid substantially more on their purchases of Temodar® than they would have paid absent Defendants' illegal conduct.

119. If manufacturers of generic versions of Temodar®, including Barr/Teva, had entered the market and competed with Defendants, Plaintiff and other Class members would have substituted lower-priced generic versions of the Drug for the higher-priced brand name Temodar® for some or all of their purchases, and/or would have received lower prices on some or all of their remaining Temodar® purchases.

VI. DEMAND FOR JURY

120. Plaintiff demands trial by jury on all issues so triable.

VII. PRAYER FOR RELIEF

121. WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully prays that:

(i) The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

(ii) The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act;

(iii) Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendants in favor of the Class;

(iv) The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

(v) The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Dated: March 5, 2010

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